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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,900	04/05/2004	Eckard Weber	2009.0010006/RWE/RAS	2634

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EXAMINER	
WINSTON, RANDALL O	
ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 03/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/816,900	WEBER ET AL.	
	Examiner	Art Unit	
	Randall Winston	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *0106,0505,0704*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Priority

This application of 10/816, 900 does not appear to be a division of Application No.10/155,171. A later application for a distinct or independent invention, carved out of a pending application and disclosing and claiming only subject matter disclosed in an earlier or parent application is known as a divisional application or "division." This application is not claiming subject matter that was restricted out in the parent application of 10/155,171 because the parent application did not contain a restriction requirement. Thus, Application No. 10/816,900 is not a divisional application of 10/155,171 because claims 33-44 of application 10/816,900 were not restricted out in the claimed parent application of 10/155,171.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 33-44 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 33-41 of copending Application No. 11/081,641 and claims 33-54 of copending Application No. 11/081,640. Although the conflicting claims are not identical, they are not patently distinct from each other because in both cases, the claims are drawn to a composition and/or solution and/or kit comprising between .00018 mg and about 0.45 mg phentolamine mesylate or a molar equivalent of another alpha adrenergic receptor antagonist and a pharmaceutically acceptable carrier present in a container that fits into a standard dental local anesthetic syringe.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 33-44 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,872,390.

Although the conflicting claims are not identical, they are not patentably distinct from each other because in both cases, the claims are drawn to a composition and/or solution comprising between .00018 mg and about 0.45 mg phentolamine mesylate or a molar equivalent of another alpha adrenergic receptor antagonist and a pharmaceutically acceptable carrier present in a container that fits into a standard dental local anesthetic syringe.

Further, the instantly claimed invention encompasses the claimed invention of 6,872,390.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 33-35, 38, 39 and 40 are rejected under 35 USC 102(b) as being anticipated by Booth et al. (US 4,508,715).

Applicant claims a composition comprising between about 0.0018 mg and about 0.45 mg phentolamine mesylate or a molar equivalent of another alpha adrenergic receptor antagonist and a pharmaceutically acceptable carrier.

Booth et al. anticipate the claimed invention (see, e.g. example IV and example IX, column 9 lines 56-59, example XII and XIV) because Booth teaches a composition comprising a molar equivalent of an alpha adrenergic receptor antagonist (i.e. 0.125 mg of yohimbine in a syringe for injection to a subject) and a pharmaceutically acceptable carrier. Therefore, the reference is deemed to anticipate the claimed invention.

Please note, the intended use of the above claimed composition (e.g. claims 38 and 39) does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use

must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting (see, e.g., MPEP 2112).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 33-40 and 42 and 43 are rejected under 35 US 103(a) as being unpatentable over Booth et al.

Applicant claims a composition and/or solution comprising between .00018 mg and about 0.45 mg phentolamine mesylate or a molar equivalent of another alpha adrenergic receptor antagonist and a pharmaceutically acceptable carrier present in a container that fits into a standard dental local anesthetic syringe for administration to a subject.

The primary reference is relied upon for the reasons discussed above. Booth et al. do not expressly teach the composition is a solution formulated for topical application and the unit dosage of the solution is present in a container that fits into a standard dental local anesthetic syringe. However, based upon the overall beneficial teachings provided by Booth et al., the result-effective adjustment of conventional working conditions therein (e.g., the substitution of one type of administration for another such

as the solution used topically instead of by injection and the form of the solution being placed in a container first than into a syringe), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the invention as a whole is prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CHRISTOPHER R. TATE
PRIMARY EXAMINER